[TAB #13]

Attachment #11

NOV 2 9 2001

Summary of 510(k) Submission

A. INFORMATION

1. SUBMITTER'S

NAME: **TILLOTSON HEALTHCARE CORPORATION**

ADDRESS: **360 Route 101**
Bedford, NH 03110 U.S.A.

TELEPHONE NUMBER: **(603) 472-6600**

CONTACT PERSON: **F.W. Perrella**

DATE SUMMARY PREPARED: **September 2001**

2. NAME OF DEVICE

TRADE OR PROPRIETARY NAME: **HPI Sensi Grip® Sterile Powdered Latex Surgical Glove, With labeled Protein Content and Made from Allotex® an Enzyme Treated Natural Rubber Latex**

COMMON OR USUAL NAME: **Surgical Glove**

CLASSIFICATION NAME: **Surgical Glove**

3. PREDICATE DEVICE IDENTIFICATION

NAME, NUMBER **HPI Ortho Surgeon's Glove (K894828)**

4. DESCRIPTION OF DEVICE

a. HOW THE DEVICE FUNCTIONS:
Natural Rubber Latex films form a barrier to body fluids and bloodborne pathogens.

b. SCIENTIFIC CONCEPTS THAT FORM THE BASIS FOR THE DEVICE:
The latex rubber is water tight under normal conditions of use. It's tensile properties cause it to conform to the hand, allowing movements necessary for a medical procedure.

c. PHYSICAL AND PERFORMANCE CHARACTERISTICS SUCH AS DESIGN, MATERIALS AND PHYSICAL PROPERTIES:
Natural Rubber Latex is known to create a barrier to bloodborne pathogens and and body fluids. ASTM conforming tensile properties create a glove that is strong and flexible. The leaching and washing process removes traces of chemical accelerants That may be chemically irritating. The glove is manufactured in accordance with the Requirements of ASTM D3577-00 and ASTM D5151-99 requirements.

5. STATEMENT OF INTENDED USE, INCLUDING DESCRIPTION OF THE DISEASES OR CONDITIONS THAT THE DEVICE WILL ADDRESS

The Sensi Grip® Surgical Glove is a disposable device intended for medical use within hospitals and other healthcare facilities during invasive and non-invasive medical procedures requiring sterility. They are intended to be worn on the operating room personnel's hand to protect a surgical wound from contamination.

6. EXPLANATION OF SIMILARITIES OR DIFFERENCES TO PREDICATE DEVICE

- **The modified product has a protein labeling claim and a raw material change whereby the natural rubber latex is treated with proteolytic enzymes to digest natural rubber latex proteins compared to the predicate product.**
- **It is a powdered surgical glove in the same way as the predicate product, but with protein content labeling, and Made from Allotex an enzyme treated natural rubber latex claim.**

B. IF THE DECISION BASED ON PERFORMANCE DATA

1. DISCUSSION OF NON-CLINICAL TESTS

SPECIFICATION	PROPOSED **Powdered** **(with protein content labeling and Made from Allotex an enzyme treated natural rubber latex claim)**	PREDICATE **Powdered**
PERFORMANCE STANDARDS	**ASTM D3577-00** **Meets or Exceeds Requirements**	**ASTM D3577-91** **Meets or Exceeds equirements**
WATER TIGHTNESS	**ASTM D5151-99** **Meets or Exceeds Requirements**	**ASTM D5151-92** **Meets or Exceeds equirements**
RESIDUAL PROTEIN	**ASTM D5712-99** **Meets or Exceeds Requirements**	

2. DISCUSSION OF CLINICAL TESTS

SPECIFICATION	PROPOSED	PREDICATE
SAFETY		
SKIN IRRITATION	**Meets or Exceeds Requirements**	**Meets or Exceeds Requirements**
SKIN SENSITIZATION	**Meets or Exceeds Requirements**	**Meets or Exceeds Requirements**

3. CONCLUSIONS DRAWN FROM NONCLINICAL AND CLINICAL TESTS THAT DEMONSTRATE
SAFETY EFFECTIVENESS, AND PERFORMANCE =/> PREDICATE PRODUCT

The HPI Sensi Grip® Powdered Sterile Surgical Glove has been carefully compared to legally marketed devices in the 510(k). The data summaries indicate that the proposed product meets or exceeds acceptable scores for the predicate product in nonclinical tests, and satisfies the requirements for a safe and effective powdered (with protein content label labeling and Made from Allotex an enzyme treated natural rubber latex claim) medical glove.

Pursuant to 21 C.F.R. 807.87 (j), I, F.W. Perrella, Ph.D., Vice President R&D certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as the Vice President R&D for TILLOTSON HEALTHCARE CORPORATION, and in reliance thereupon, the data and information submitted in this of the substantial equivalence of this device have been knowingly omitted from this Submission.

F.W. Perrella, Ph.D.
Vice President R&D F.W. Perrella

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2001

Dr. Frank W. Perrella
V.P. Research and Development
Tillotson Healthcare Corporation
360 Route 101 W
Bedford, New Hampshire 03110

Re: K013324
Trade/Device Name: HPI Sensi Grip Powdered Latex Surgical Gloves made from Allotex (enzyme treated) natural rubber latex with a Protein Content Labeling Claim (50 Micrograms or Less per gram of glove)
Regulation Number: 878.4460
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: KGO
Dated: September 30, 2001
Received: October 5, 2001

Dear Dr. Perrella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.0 Indications for Use Statement: Include the following or equivalent Indications for Use page. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the Indications for Use statement.

INDICATIONS FOR USE

Applicant: Tillotson Healthcare Corporation

5 10(k) Number (if known):*

Device Name: **HPI Sensi Grip® Sterile Powdered Latex Surgical Glove, With labeled Protein Content and Made from Allotex® an Enzyme Treated Natural Rubber Latex** (50 micrograms or less)

Indications For Use: **The Sensi Grip® Surgical Glove is a disposable device intended for medical use within hospitals and other healthcare facilities during invasive and non-invasive medical procedures requiring sterility. They are intended to be worn on the operating room personnel's hand to protect a surgical wound from contamination.**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH Office of Device Evaluation (ODE)

Olin S. Lin

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013324

Prescription Use _____ OR Over-The-Counter _____
Per 21 CFR 801.109
(Optional Format 1-2-96)

For a new submission, do **NOT** fill in the 510(k) number blank.